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EXAMINER	
SCHELL, LAURA C	

ART UNIT	PAPER NUMBER
3767	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/755,249	MAWAD, MICHEL E.	
	Examiner	Art Unit	
	Laura C. Schell	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 May 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-34* is/are pending in the application.

4a) Of the above claim(s) *11-21* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10 and 22-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *12 January 2004* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/1/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "injector" in claims 1 and 30 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: Claims 1 and 30 recite "an injector", however there is no reference to "an injector" in Applicant's specification. Claim 27 recites "a combination of contact ... and application of a controlled stimulus", however there is no reference a combination of contact and controlled stimulus effecting an expanded size, in Applicant's specification.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 27 and 30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In reference to claim 1, lines 8-9 recite "an injector configured to release embolic material proximate said distal end of said flexible tubular member and into the vessel". The examiner, however, has been unable to find support in Applicant's specification for "an injector".

In reference to claim 27, lines 2-3 recite "reaches its expanded size in response to a combination of contact with an in vivo environment in the vessel and application of a controlled stimulus". The examiner, however, has been unable to find support in Applicant's specification for "a combination" of the contact and controlled stimulus.

In reference to claim 30, lines 1-2 recite "an injector configured to inject an embolic material from said distal end of said flexible tubular member into the vessel". The examiner, however, has been unable to find support in Applicant's specification for "an injector".

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 29 and 33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 29 and 33 recites the limitation "the space" in lines 6, 7 and 9, respectively. There is insufficient antecedent basis for this limitation in the claim.

In further reference to claim 33, lines 8-10 state that the expansible portion expands to occlude "the space between said circumference of said elongated tubular member and the vessel". This wording does not seem to be accurate, as there is no space between the circumference of the tubular member and the vessel because the expansible portion occupies this space in order for expansible portion to be able to occlude the vessel. It would seem that better phrasing, such as "the space between the expansible portion and the vessel" would be more accurate and less confusing.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 8, 10, 22-24 and 28 are rejected under 35 U.S.C. 102(e) as being anticipated by Tran et al. (US Patent No. 7,229,454). Tran discloses a catheter (Figs. 1-3, 8-10 and 18, for example) for providing an embolic material at a desired location in a vessel (abstract), comprising: a flexible tubular member (Fig. 1, 100) having a proximal end (near 110), a distal end (near 140a) and an outer surface, said tubular member including at least one ring of expansible material affixed to its outer surface (130 is a ring affixed to the outer surface of the tubular member. The Merriam-Webster online dictionary's definition of "expansible" is "capable of being expanded" {http://www.m-w.com/cgi-bin/dictionary?book=Dictionary&va=expansible} and as col. 6, lines 18-20 disclose, ring 130 is expandable, and therefore expansible) proximate said distal end, wherein said at least one ring has an expanded size which occludes a space between the outer surface and the vessel (Figs. 7-9 disclose that the ring (130) expands to occlude the space between 130 and the vessel 190); an injector (col. 4, lines 25-30)

configured to release embolic material proximate said distal end of said flexible tubular member and into the vessel (col. 7, lines 21-25); and wherein the embolic material and the at least one ring occlude the vessel (abstract).

In reference to claim 8, Tran discloses that the ring (130) is affixed to said tubular member adjacent to said distal end (Fig. 1).

In reference to claim 10, Tran discloses that multiple radioopaque markers are spaced along the tubular member at predetermined intervals (col. 5, lines 2-5).

In reference to claim 22, Tran discloses that the embolic material contacts the at least one expansible ring after the material is released into the vessel (Figs. 8 and 9; col. 7, lines 17-21).

In reference to claim 23, Tran discloses that the at least one ring is detachable from said tubular member while the tubular member is at the desired location within the vessel (abstract).

In reference to claim 24, Tran discloses that the at least one ring of expansible material reaches its expanded size in response to application of a controlled stimulus (col. 6, lines 18-22 disclose that the ring is expanded upon the controlled filling of liquid, which is therefore the controlled stimulus).

In reference to claim 28, Tran discloses that the combination of said at least one ring of expansible material in its expanded size and said embolic material occludes the vessel (abstract and Figs. 8 and 9).

Claims 29-31 are rejected under 35 U.S.C. 102(e) as being anticipated by Tran et al. (US Patent No. 7,229,454). Tran discloses a catheter (Figs. 1-3, 8-10 and 18, for example) for providing an embolic material at a desired location in a vessel (abstract), comprising: a flexible tubular member (Fig. 1, 100) having a proximal end (near 110), a distal end (near 140a), and an external surface, said flexible tubular member further having an expansible portion (130 is a ring affixed to the outer surface of the tubular member. The Merriam-Webster online dictionary's definition of "expansible" is "capable of being expanded" {http://www.m-w.com/cgi-bin/dictionary?book=Dictionary&va=expansible} and as col. 6, lines 18-20 disclose, ring 130 is expandable, and therefore expansible) adjacent said distal end; and wherein said expansible portion has a resting size (Fig. 1), said resting size closely approximating said external surface of said flexible tubular member and said expanded size (Figs. 8 and 9) being sufficient to occlude the space between said flexible tubular member and the vessel (Figs. 8 and 9 disclose that 130 occludes the member when expanded); and wherein said expansible portion is detachable from said flexible tubular member while said flexible tubular member is at the desired location in the vessel (abstract discloses that the expansible portion is detachable).

In reference to claim 30, Tran discloses an injector (col. 4, lines 25-30) configured to inject embolic material from said distal end of said flexible tubular member into the vessel (col. 7, lines 21-25).

In reference to claim 31, Tran discloses that the expansible portion expands from said resting size to said expanded size in response to application of a controlled

stimulus (col. 6, lines 18-22 disclose that the ring is expanded upon the controlled filling of liquid, which is therefore the controlled stimulus).

Claims 33 and 34 are rejected under 35 U.S.C. 102(e) as being anticipated by Tran et al. (US Patent No. 7,229,454). Tran discloses a catheter (Figs. 1-3, 8-10 and 18, for example) for providing an embolic material at a desired location in a vessel (abstract), comprising: an elongated tubular member (Fig. 1, 100) having a proximal end (near 110), a distal end (near 140a), and a circumference, said elongated tubular member further having an expansible portion comprising an expandable material (130 is a ring affixed to the outer surface of the tubular member. The Merriam-Webster online dictionary's definition of "expansible" is "capable of being expanded" {http://www.m-w.com/cgi-bin/dictionary?book=Dictionary&va=expansible} and as col. 6, lines 18-20 disclose, ring 130 is expandable, and therefore expansible) about said circumference and proximate said distal end; and wherein said distal end is configured to permit embolic material to be placed in the vessel through said distal end (col. 4, lines 25-30 and col. 7, lines 21-25); wherein said expansible portion is configured to expand from a first position (Fig. 1) to a second position (Figs. 8 and 9) occluding the space between said circumference of said elongated tubular member and the vessel (Figs. 8 and 9 disclose that 130 occludes the member when expanded); wherein said embolic material and said expansible portion in said second position occlude the vessel (Figs. 8 and 9 and abstract); and wherein said expansible portion is detachable from said elongated

tubular member while said elongated tubular member is at the desired location in the vessel (abstract).

In reference to claim 34, Tran discloses that the expansible portion is detachable from said elongated tubular member while at the desired location in the vessel (abstract).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 6, 7 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tran et al. (US Patent No. 7,229,454). Tran discloses the device substantially as claimed, however Tran does not disclose the distance the ring is fixed from the distal end. It would have been obvious to one of ordinary skill in the art at the time of the

invention to have modified the distance between the ring and the distal end to optimize its placement and consequently its effectiveness, since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. In re Rose, 105 USPQ 237 (CCPA 1955).

Claims 2-4, 26 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tran et al. (US Patent No. 7,229,454) in view of Mehta (US Patent No. 5,258,042). Tran discloses the device substantially as claimed except for the ring being comprised of a material that expands in volume when in contact with a liquid, or a hydrogel, the time it takes for expansion or that the expansion occurs in response to an in vivo environment. Mehta, however, discloses an expansible ring of hydrogel material on the circumference of a catheter for occlusion (abstract). Mehta further discloses that the ring expands in less than 20 minutes (col. 6, lines 41-42), which falls within the 10-30 minute time frame claimed. Mehta also discloses that the expansible material reaches its expanded size in response to an in vivo environment within the vessel (col. 6, lines 40-43). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Tran with the hydrogel ring, in order to provide an occluder that expands by itself for simplification of the procedure.

Claims 9 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tran et al. (US Patent No. 7,229,454) in view of Rosenthal et al. (US Patent No.

7,066,904). Tran discloses the device substantially as claimed including an expansible ring (130), however, Tran does not disclose that the ring expands in response to an application of heat and/or the combination of contact with an in vivo environment and application of a controlled stimulus. Rosenthal, however, discloses that the material expands in volume when it contacts with a liquid and when exposed to heat (col. 6, lines 57-64). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Tran with use of applied stimulus for expansion of the ring, in order to provide a ring/member that can be better controlled during the procedure.

Response to Arguments

Applicant's arguments with respect to claims 1-10, 22-34 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura C. Schell whose telephone number is (571) 272-7881. The examiner can normally be reached on Monday-Friday 9am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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